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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,922	10/06/2003	Nilesh Balar	H-541	1407

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/678,922	Applicant(s) BALAR ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 06 September 2006.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 1-6 is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 09/06/06 is acknowledged.

Applicant has overcome the following rejection(s):

The 35 U.S.C. §103(a) rejection of claims 1-6 over Shibuya (US Pat. Appln. Pub. '759) in view of Shaw *et al.* (USPN '869) has been withdrawn.

Claims 1-6 are pending in this action. Claims 1 and 4 have been amended. Claims 1-6 remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d

1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention/(5) The breadth of the claims:

The invention is directed to a suture, graft or suture/graft combination comprising PTFE and having a polymer coating containing releasable biological agents for the prevention and reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted, or injured area of a vessel or arterial wall. The invention is also directed to a suture, graft or suture/graft combination comprising PTFE having a reservoir containing releasable biological agents for the prevention and reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted, or injured area of a vessel or arterial wall, said biological agent being osmotically released through the pores in the reservoir.

(2) The state of the prior art:

The prior art teachings provide for sutures/grafts coated with biologically active compounds for the treatment of intimal smooth muscle hyperplasia, restenosis, vascular occlusion and the like.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

The predictability of the art is high.

(6) The amount of direction or guidance presented:

The specification filed 10/06/03, discloses 'preventing or reduction' of intimal hyperplasia and smooth muscle cell proliferation. It is unclear to the Examiner as to how the instant suture, graft or suture/graft combination provides for the "*prevention*" of intimal hyperplasia and smooth muscle cell proliferation. While the 'reduction' or 'treatment' of intimal hyperplasia and smooth muscle cell proliferation is known in the art, 'prevention' of intimal hyperplasia and/or smooth muscle cell proliferation is not known, nor recognized in the art. The specification provides no guidance on how the "prevention" of intimal hyperplasia and/or smooth muscle cell proliferation can be provided through the instantly claimed suture, graft or suture/graft combination.

(7) The presence or absence of working examples:

The working examples are insufficient to establish the instant suture, graft or suture/graft combination that provides for the "prevention" of intimal hyperplasia and smooth muscle cell proliferation.

(8) The quantity of experimentation necessary:

The instant invention provides for a suture, graft or suture/graft combination comprising PTFE and having a polymer coating containing releasable biological agents for the prevention and reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted, or injured area of a vessel or arterial wall. The invention also provides for a suture, graft or suture/graft combination comprising PTFE having a reservoir containing releasable biological agents for the prevention and reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted, or injured area of a vessel or arterial wall, said biological agent being osmotically released through the pores in the reservoir. When the above factors are weighed together, it is the position of the Examiner that the instant invention would require 'undue' and painstaking experimentation to arrive at a suture, graft or suture/graft combination that effectively reduces intimal hyperplasia or smooth muscle cell proliferation, with the "prevention" of intimal hyperplasia or smooth muscle cell proliferation being even less likely or probable.

It is suggested that the term "*prevention*" in instant claims 1 and 4 be deleted, in order to overcome the 112 1st, enablement rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaw *et al.* (U.S. Pat. No. 6,918,869 B2).

The instant invention is drawn to a suture, graft or suture/graft combination comprising PTFE and having a polymer coating containing releasable biological agents for the prevention and reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Shaw *et al.* ('869) disclose a system to provide treatment of intimal hyperplasia and smooth muscle cell proliferation, which cause stenosis or restenosis of a body lumen (see column 3, lines 37-43). The system includes devices such as grafts (arterial, venous, non-vascular, vascular (col. 5, lines 36-43); (col. 7, line 62 – col. 8, line 8). Useful and suitable polymers disclosed include polypropylene (col. 8, line 29 – col. 9, line 39).

Shaw *et al.* disclose that graft coverings may provide for localizing the biologically active material at the ends of a medical device. Graft coverings are strips of fabric, such as Dacron or *PTFE* that are used to hold the biologically active material in a matrix. Graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). Grafts may also be sutures or strips attached or interwoven into the ends of a stent, which hold the biologically active material (col. 13, lines 57-67).

Suitable biologically active agents disclosed include taxol (col. 22, line 47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Narayanan (US Pat. No. 6,919,100 B2) in view of Shaw *et al.* (U.S. Pat. No. 6,918,869 B2).

The instant invention is drawn to a suture, graft or suture/graft combination having a polymer coating containing releasable biological agents for the prevention and reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Narayanan ('100) discloses coated medical devices and a process for coating medical devices, used to treat a particular condition (see Abstract). The method comprises the steps of preparing an aqueous latex polymeric emulsion, adding at least one drug, agent and/or compound, in therapeutic dosages, to the aqueous latex polymeric emulsion for the treatment of a predetermined condition (col. 2, lines 56-62).

Medical devices that comprise the coatings include grafts, sutures, suture anchors and the like (col. 3, line 65 – col. 4, line 29).

Therapeutic agents that can be delivered through the coatings include paclitaxel, antibiotics (*i.e.*, dactinomycin), etc. (col. 4, line 30 – col. 5, line 16). Rapamycin is disclosed at column 9, lines 17-39. Rapamycin inhibits the proliferation of vascular smooth muscle cells in vivo. Accordingly, rapamycin may be utilized in treating intimal smooth muscle hyperplasia, restenosis and vascular occlusion in a mammal, particularly following biologically or mechanically mediated vascular injury. Rapamycin functions to inhibit smooth muscle cell proliferation and does not interfere with re-endothelialization of the vessel walls (col. 9, lines 16-28). Rapamycin also prevents T-cell proliferation when administered systemically. This is the basis for its immunosuppressive activity and its ability to prevent graft rejection (col. 9, lines 35-38). In preferred embodiments, rapamycin is incorporated onto the surface of the stent or portions thereof (col. 9, lines 51-53).

Regarding the limitation 'plasma-assisted coating' claimed in instant claim 2, the 'plasma-assisted coating' is a future-intended use limitation, which affords no patentable weight to the claims.

Narayanan does not teach that the suture/graft comprises PTFE.

Shaw ***et al.*** **('869)** teach a system to provide treatment of intimal hyperplasia and smooth muscle cell proliferation, which cause stenosis or restenosis of a body lumen (see column 3, lines 37-43). The system includes devices such as grafts (arterial, venous, non-vascular, vascular (col. 5, lines 36-43); (col. 7, line 62 – col. 8, line 8). Useful and suitable polymers disclosed include polypropylene (col. 8, line 29 – col. 9, line 39). Shaw *et al.* disclose that graft coverings may provide for localizing the biologically active material at the ends of a medical device. Graft coverings are strips of fabric, such as Dacron or *PTFE* that are used to hold the biologically active material in a matrix. According to Shaw *et al.*, the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). Grafts may also be sutures or strips attached or interwoven into the ends of a stent, which hold the biologically active material (col. 13, lines 57-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the PTFE (or polypropylene) of Shaw *et al.* within the suture/grafts of Narayanan. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Shaw *et al* teach that graft coverings that can be utilized include PTFE to hold the biologically active material in a matrix and teach that the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). The expected result would be an improved suture graft material for the effectively treating or reducing intimal hyperplasia and/or smooth muscle cell proliferation.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollison *et al.* (US Pat. No. 6,890,546 B2) in view of Shaw *et al.* (U.S. Pat. No. 6,918,869 B2).

The instant invention is drawn to a suture, graft or suture/graft combination having a polymer coating containing releasable biological agents for the prevention and reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Mollison *et al.*, as delineated above, teach a medical device comprising a supporting structure having a coating on the surface thereof, the coating containing a therapeutic substance, as a drug. Supporting structures for the medical devices include arterio-venous grafts and by-pass grafts (see Abstract); (col. 4, lines 57-65).

Mollison *et al.* also teach a method of treating a variety of disease states, including restenosis, post-transplant tissue rejection, immune and autoimmune dysfunction, fungal growth and cancer (col. 4, lines 53-56).

More particularly, the invention relates to semisynthetic analogs of rapamycin, means for their preparation, pharmaceutical compositions containing such compounds and methods of treatment employing the same (col. 1, lines 15-22).

Coatings suitable for use in the invention include polymeric coatings that can comprise any polymeric material in which the therapeutic agent is substantially soluble. The coating can be hydrophilic, hydrophobic, biodegradable or non-biodegradable. This medical device reduces restenosis in vasculature (col. 6, lines 40-49).

Hyperproliferative vascular diseases that can be treated include smooth muscle cell hyperplasia, restenosis and vascular occlusion, particularly following biologically- or mechanically-mediated vascular injury (col. 11, lines 48-53). Additionally, compounds of the invention possess FK-506 antagonistic properties. The compounds of the invention may be used to treat disorders involving immunodepression, including AIDS, cancer, fungal infections and trauma (including wound healing, surgery and shock) (col. 13, line 62 – col. 14, line 29).

In addition to stents, other devices used to introduce drugs to the vasculature include *grafts*, catheters and balloons (col. 11, lines 64-66).

According to Mollison *et al.*, the coating can comprise any polymeric material. The purpose of the coating is to serve as a controlled release vehicle for the therapeutic agent or as a reservoir for a therapeutic agent to be delivered at the site of a lesion (col. 12, lines 2-7).

Regarding the limitation 'plasma-assisted coating' claimed in instant claim 2, the 'plasma-assisted coating' is a future-intended use limitation, which affords no patentable weight to the claims.

Mollison *et al.* do not teach PTFE.

Shaw *et al.* ('869) teach a system to provide treatment of intimal hyperplasia and smooth muscle cell proliferation, which cause stenosis or restenosis of a body lumen (see column 3, lines 37-43). The system includes devices such as grafts (arterial, venous, non-vascular, vascular (col. 5, lines 36-43); (col. 7, line 62 – col. 8, line 8). Useful and suitable polymers disclosed include polypropylene (col. 8, line 29 – col. 9, line 39). Shaw *et al.* disclose that graft coverings may provide for localizing the biologically active material at the ends of a medical device. Graft coverings are strips of fabric, such as Dacron or *PTFE* that are used to hold the biologically active material in a matrix. According to Shaw *et al.*, the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). Grafts may also be sutures or strips attached or interwoven into the ends of a stent, which hold the biologically active material (col. 13, lines 57-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the PTFE (or polypropylene) of Shaw *et al.* within the graft sytems of Mollison *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Shaw *et al* teach that graft coverings that can be utilized include PTFE to hold the biologically active material in a matrix and teach that the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). The expected result would be a highly effective graft material for the treatment or reduction of intimal hyperplasia and/or smooth muscle cell proliferation, as similarly desired by Applicant(s).

Response to Arguments

Applicant's arguments filed 09/06/06 have been fully considered but they are not persuasive.

- **35 U.S.C. §112, 1st paragraph rejection:**

Applicant argued, "It is widely known that smooth cell production and proliferation causes intimal hyperplasia in the injured vessel. Thus reduction in SMC proliferation would implicitly prevent intimal hyperplasia and thereby reduce its formation. Applicants contend that the drugs act on the injured tissue cells; the action of the claimed drugs is to reduce or inhibit SMC proliferation and consequently prevent intimal hyperplasia. Applicants do not claim suppression of intimal hyperplasia *ab initio*. Stated differently, prevention is an inherent function of the drug that further leads to reduction of intimal hyperplasia. More explicitly, reduction of intimal hyperplasia occurs by preventing its formation and not by its shrinkage or removal after it is formed.

Applicants argue that the superior osmotic elution of the drugs from the instant porous sutures and the controlled diffusion from the polymer coated sutures result in a greater degree of preventive action than can be expected from commercially available sutures or grafts comprising smooth-walled materials."

Applicant's arguments have been thoroughly considered, but were not persuasive. While it is agreed that "*prevention*" of intimal hyperplasia may be an inherent factor upon reduction of SMC proliferation, nonetheless, the claims when reciting "prevention" of a particular disease or condition renders the claims non-enabling. According to PTO practice, while claim language such as 'treatment' or 'reduction' of a particular disorder or disease is accepted, the language utilizing "*prevention*" raises a cloud over the issue of enablement and is not permissible in the claims. Examiner again suggests deletion of the term "*prevention*" to overcome the enablement rejection.

- **35 U.S.C. §103(a) rejection of Claims 1-6 over Shibuya (US 2002/0055759) in view of Shaw et al. (6,918,869):**

Applicant argued, "The Shibuya reference is directed to an entirely different process in the art. Shibuya does not teach the instant suture material, PTFE, recited in independent claims 1 and 4. Shibuya has no reference to grafts or suture/graft combinations. While the biological compounds of Shibuya are alleged to be curative, they do not prophylactically reduce smooth muscle cell proliferation and does not address reduction of intimal hyperplasia. Shibuya does not teach a reservoir containing releasable biological agents. It does not teach rapamycin, taxol, derivatives of taxol and rapamycin and combinations thereof. These drugs are particularly targeted to reduce SMC proliferation and intimal hyperplasia and belong to a different class from those listed by Shibuya."

Applicant's arguments have been considered and were found persuasive. Accordingly, the 35 U.S.C. §103(a) rejection of claims 1-6 over Shibuya in view of Shaw et al. has been withdrawn.

- **35 U.S.C. §103(a) rejection of Claims 1-6 over Mollison et al. (6,890,546) in view of Shaw et al. (6,918,869) and Claims 1-6 over Narayan (6,919,100) in view of Shaw et al. (6,918,869):**

Applicant argued, "The instant invention narrowly claims porous PTFE sutures with specific biological coatings for reduction of intimal hyperplasia and inhibition of SMC proliferation. Applicants believe, respectfully, that Examiner's deft use of the term "graft" is disingenuous. As stated by the Examiner in the §112 rejection, the relative skill of those in the art is high. One of such skill would be able to distinguish between (smooth) grafts used to cover the ends of implanted devices such as stents and catheters as disclosed in Shaw (col. #13, 55-67) from those recited in the instant disclosure wherein the suture or graft is placed directly over injured vessels to deliver drugs locally (p.8, lines 10-20). The porous structures of the instant grafts and sutures may not provide the smooth abrasion-lowering characteristics required for Shaw's application. This is also apparent from Shaw's use of the term "graft" (col. #13; lines 65-67) in quotes suggesting an unconventional use of the term for strips of polymers and sutures woven together at the ends of a stent. Applicants agree and state in the disclosure that devices coated with biologically active agents are known in the art and include sutures and grafts. These are known, smooth-walled materials, which do not hold or deliver the drugs as efficaciously as the instant claimed sutures and grafts. Further, neither Shibuya nor Shaw teaches a PTFE suture or graft or suture-graft combination with a polymer coating, which carries the biologically active drug as recited in claim 1. They do not teach delivering drugs from a reservoir on the sutures or grafts as claimed in claim 4. Examiner's contention that one would be motivated to use e-PTFE (expanded PTFE) as taught by Shaw in Shibuya's sutures is unconvincing and an improper combination derived from the instant disclosure. As argued above, Shaw's sutures, designed to minimize abrasion, are not as effective as the instant polymer-coated sutures or reservoir-bearing grafts and sutures. The primary references do not teach a PTFE-suture or graft. The motivation for incorporating Shaw's PTFE (which is used to cover the ends of stents and catheters and thereby provide a smooth abrasion-free insert) is not tenable in case of bare sutures and grafts which are placed directly over injured body lumen. It is not clear to Applicants that the smooth-walled PTFE required for Shaw's application would provide the same efficacy of a porous PTFE carrier, which may further carry a polymer coating or a reservoir. Neither the primary references nor Shaw teaches a plasma-assisted polymer coating on the PTFE suture or graft. Thus, even if one were to substitute the sutures and grafts of the primary references with PTFE, it would not lead to the instant invention."

Applicant's arguments have been considered, but were found unpersuasive. The argument that the "instant suture or graft is placed directly over injured vessels to delivery drugs locally" was not persuasive since nowhere in the claims does the recitation exist that the "suture/graft has a direct placement over injured vessels". Thus, Applicant's arguments do not establish the scope of claims being presented. Moreover, a composition is being claimed and it is the patentability of the composition that needs to be established. Particular placement or location of the suture/graft does not impart patentability to the claims. Furthermore, the prior art is aimed at treating similar problems as that desired by Applicants, such as the reduction or mitigation of hyperplasmic conditions. Applicant's argument that the "smooth-walled materials do not hold or deliver drugs in an efficacious manner" was not persuasive since the instant claims are completely silent with regards to any desired amount of drug to be delivered. The claims lack any specific dosage or regimen amounts of drug delivery.

Applicant's argument that "Shaw's sutures are designed to minimize abrasion, and are not as effective as the instant polymer-coated sutures or reservoir-bearing grafts and sutures" was not persuasive since Applicants have not clearly demonstrated or established any superior or unexpected results attributable to the claimed suture, suture/graft devices over the teachings of the art. Moreover, the Shaw reference does recognize and teach the same polymer, PTFE for use in suture/graft devices, albeit for covering ends of stents and catheters. At present, the instant claims remain generic enough to read on the teachings of the cited art.

Applicant argued, "Examiner contends that the limitation "plasma-assisted coating" (instant claim 2) is a future-intended use limitation that adds no patentable weight to the claim". Applicants vigorously disagree. The instant claims are directed to an article of manufacture; viz., a PTFE-suture coated with a polymer that carries biologically active agents. As disclosed by Applicants (p.12, lines 8-16), plasma-assisted coatings provide for complex drug delivery strategies that other coating techniques do not. This is a critical feature of the instant invention. In addition to being able to regulate drug delivery through altered surface chemical activity and the like, plasma assisted coatings provide uniform, thin coatings of controlled thickness. Applicants have recognized the versatile properties of plasma assisted coatings and have adopted them for their drug delivery on sutures and grafts. Applicants once again agree that there are diverse drug-eluting sutures and grafts, as disclosed by Shibuya and Shaw (above) and numerous methods of providing the drug coating on the sutures and grafts. The instant sutures and grafts comprising PTFE with plasma-assisted polymer coating are not taught or suggested either individually or in combination by the references cited."

Applicant's arguments have been considered, but were found unpersuasive. Applicant's remarks stating beneficial effects of a 'plasma-assisted' coating do not represent the scope of claims being presented. The claims remain generic in the sense that they do recite any specific compositions having any specific coating thicknesses claimed. The term 'plasma-assisted coating' remains a relative feature in the claims. The claims are broad enough to be met by the explicit teachings of the art, absent evidence to the contrary. No patentable invention is seen in the use of the 'plasma-assisted coatings' since the prior art vividly teaches suture/graft therapeutic devices for local drug delivery comprising similar components (*i.e.*, drugs, polymer) as claimed, for use in the same field of endeavor as Applicant and to treat similar problems as claimed (*i.e.*, hyperplasia).

Absent a showing of unexpected results, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, based on the disclosure of the cited art delineated above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Primary Examiner
Art Unit 1615
December 7, 2006

Humera N Sheikh
HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

hns